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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,365	06/19/2001	Mark A. Reiley	1759.2570-CIP 4 CON	3566
26308	7590	04/23/2004	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 04/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,365

Applicant(s)

REILEY ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (5,108,404) in view of Wang et al. (5,403,340). Scholten et al. disclose the invention substantially as claimed. Scholten et al. disclose, in figures 21-24 and 33 and in col. 7, lines 27-35 and col. 8, line 49 to col. 9, line 17, a method for treating bone comprising inserting inside a bone (e.g., 66) with an interior volume of at least in part, cancellous bone, expanding a body (e.g. 76) in cancellous bone for compacting the cancellous bone, and removing the body from the bone. However, Scholten et al. do not disclose a void created by the expanded body that is less than the interior volume, where the void volume occupies a percentage of the interior volume as claimed. Scholten et al. do not disclose plastic deformation of the body during cancellous bone

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compaction, instructing against reuse of the plastically deformed body, and displacement of cortical bone during body expansion. Scholten et al. also do not disclose vinyl, nylon, polyethylene, an ionomer, polyurethane, polyethylene, and tetraphthalate and expandable body materials. Wang et al. teach, in col. 2, lines 11 to col. 3, line 16 and col. 5, lines 57-62, balloons or expandable bodies comprising materials as claimed, where the bodies can include plastically deformed, "non-compliant" balloons. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wang et al., to apply a plastically deformed or "non-compliant" expandable body, or at least a body having a plastically deformed or "non-compliant" expansion phase, in the method of Scholten et al. Such a body has the hardness and rigidity and shape retention, in its fully-expanded condition, for compacting cancellous bone to a desired bone cavity size and shape. Also, it would be a matter of design choice to choose one of the materials as claimed for the expandable body. The choice would be dependent upon the desired amount of compliance (i.e., range of radial expansion) for the size and type of bone being treated. It would also be obvious to instruct against reuse of the plastically deformed body. A plastically deformed or "non-compliant" body can only compact cancellous bone to a relatively fixed geometry, and if a larger cavity is desired or if "recoil" of the cancellous bone into the cavity occurs, another expandable body of a larger size, shape, or compliance curve; would be necessitated for the cancellous bone compaction. Also, it would be a matter of design choice to create a void in bone that has a volume less than the interior volume. The choice of void volume would be dependent upon the size and type of

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bone, the nature of the bone wounds, and the amount of filling material necessary for the bone treatment. A void with a volume less than the interior volume could be chosen for a substantially healthy bone requiring only minor filling or repair. Finally, it would have been obvious to use the expandable body for displacement of cortical bone sections. One of the objects of the method of Scholten et al. is the repair of bone fractures, which includes fragmented cortical bone overlying the cancellous bone. Repair of the bone includes reducing the fractures, which entails shifting or displacing cortical bone fragments and the attached cancellous bone, internally (with, e.g., an expandable body or rods) and externally (with, e.g., plates or splints), until the bone reaches its proper geometry.

3. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. in view of Wang et al. as applied to claims 7 and 9 above, and further in view of Levy. Scholten et al. in view of Wang et al. disclose the invention substantially as claimed, but do not disclose a body made of latex or silicone. Levy (4,490,421) teaches, in col. 1, lines 24-39, the use of latex ("thermoplastic rubbers") and silicone ("silicone polycarbonate copolymers") in balloon catheters. It would have been a matter of design choice to apply latex or silicone in the expandable body of Scholten et al. in view of Wang et al. The choice would be dependent upon the desired amount of compliance (i.e., range of radial expansion) for the size and type of bone being treated.

Response to Amendment

4. Applicant's arguments filed on February 17, 2004 have been fully considered but they are not persuasive. See the rejections above.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

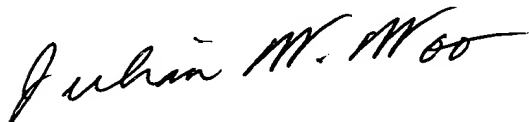
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

April 20, 2004